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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,466	06/27/2003	Laszlo Vertesy	DEA V2002/0046US NP	9365

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EXAMINER	
OH, TAYLOR V	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,466	VERTESY ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23* is/are allowed.

6)☒ Claim(s) *1-4,7,9 and 16-21* is/are rejected.

7)☒ Claim(s) *5,6,8,10-15 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

The Status of Claims:

Claims 1-23 are pending.

Claims 1-4, 7, 9, and 16-21 have been rejected.

Claims 5-6, 8, 10-15 and 22 are objected.

Claim 23 is allowable.

DETAILED ACTION

Priority

Claims 1-23 are under consideration in the application.

I It is noted that this application claims a benefit of 60/423,473 (11/04/02); the examiner has acknowledged that foreign priority documents, Germany 10229713.4 (7/2/02) has been filed.

Drawings

II None.

Claims 5-6, 8, 10-15, and 20-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 22 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 22, which depends on claim 1 and claim 21, which refers to two sets of claims to two different features. See MPEP § 608.01(n). Accordingly, the claim 22 is not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some anti-bacterial infections does not reasonably provide enablement for all the anti-bacterial infections ,such as Bacillus

subtilis . Although the claims are directed to the general anti-bacterial treatment of in a patient in need, the specification falls short because data essential for treating all kinds of anti-bacterial infections by means of administering the compounds of serpentemycins is not described in the specification.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The Nature of the Invention

The nature of the invention in claims 20 and 21 is the method for treating bacterial disease by using administering the compounds of serpentemycins of formula (I).

The State of the Prior Art

The state of the prior art is the followings:

[0005] A relatively large number of polyene antibiotics, most of which are macrolides, that is their structures belong to the macrocyclic structure type, have already been described. These macrolides act antimycotically by means of interactions with biological membranes, and are, therefore, toxic to warm-blooded animals (homeotherms). The most important representative of this antibiotic type is amphotericin B, which is used as a therapeutic agent in humans despite its toxicity. An example of a nonmacrocyclic polyene antibiotic which has been described (Ritzau et al., Liebigs Ann. Chem. 1993, 433-435) is serpentene, which contains a phenyl ring which is substituted in the 1,2 position by polyene side chains. In tests directed against Gram-positive and Gram-negative bacteria, serpentene only exhibited a weak antibiotic effect against *Bacillus subtilis*.

From this, there is no conclusive evidence that the serpentemycins of formula (I) can treat all the known bacterial diseases.

The predictability or lack thereof in the art

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the application of the serpentemycins of formula (I) would result in only the specific sites of the celluar membranes; this kind of treatment can not translated to the possible treatment of all the known bacterial diseases.

Hence, in the absence of a showing of correlation among all the known bacterial diseases claimed as capable of treatment by the compound of the serpentemycins of formula (I), one of skill in the art is unable to fully predict possible results from the administration of the claimed serpentemycins of formula (I) due to the unpredictability of the role of the serpentemycins of formula (I), i.e. whether the serpentemycins of formula (I) would be useful in treating all the known bacterial diseases.

The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present

The direction present in the instant specification is that the serpentemycins of formula (I) can treat some gram positive and gram negative bacteria. However, the specification is silent and fails to provide guidance as to whether all the bacterial infections require the presence of the serpentemycins of formula (I) for treatment, i.e. the specification fails to provide a correlation between those bacterial infections and the the serpentemycins of formula (I) that would lead to the direction and guidance for treatment of any kinds of bacterial infections.

The presence or absence of working examples

There are some working examples using the culture of Actinomycetales to see the effectiveness of the anti-bacterial treatment . Furthermore, there are working examples for fluorescence intensity measurement of the serpentemycins of formula (I). However, the serpentemycins of formula (I) which is disclosed in the specification has no pharmacological data regarding the treatment of all kinds of bacteria besides the culture of Actinomycetales (see pages 17-19 ,examples 1-5) . Also, the specification fails to provide enough working examples as to how all kinds of the bacterial disease can be treated by the application of the serpentemycins of formula (I) ,i.e. again, there is no correlation between the abnormalities of the urinary bladder and the application of the serpentemycins of formula (I).

The breadth of the claims

The breadth of the claims is that the serpentemycins of formula (I) can treat all kinds of the bacterial disease , without sufficient evidence to prove the applicability of the serpentemycins of formula (I) to all kinds of the bacterial disease .

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what the all kinds of the bacterial disease would be benefited by the application of the serpentemycins of formula (I) would furthermore then have to determine whether the claimed compound would provide the treatment for all kinds of the bacterial disease.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine whether or not the serpentemycins of formula (I) exhibits the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the the serpentemycins of formula (I) for the treatment of any baterial infections. As a result, necessitating one of skill to perform an exhaustive search for which diseases can be treated by the serpentemycins of formula (I) in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 20, the phrase " an antibacterially effective amount" is recited. This is vague and indefinite because the specification does not elaborate what is meant by the phrase " an antibacterially effective amount". Therefor, an appropriate correction is required.

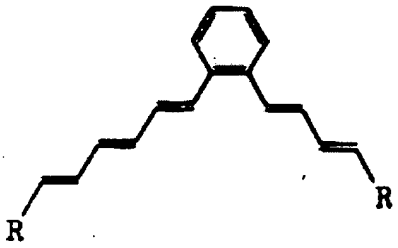
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 7, and 9 are rejected under 35 U.S.C. 102(a) as being anticipated clearly by Darby et al (J. of Organic Chemistry, 1977,42(11), p.1960-7).

Darby et al discloses the following compound (see page1962, scheme IV):



37, R = $COOC_2H_5$

This is identical with the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*** 8/21/08